

## **REMARKS**

### **Amendments to the Claims**

Claims 1-13 are pending. Claims 2-5 were withdrawn without traverse. Claims 1 and 12 are currently amended and Claim 13 is new.

Regarding the amendments to claim 1: the feature “large number of membrane elements” was objected to as indefinite, the feature was hereby amended to recited “a plurality of membrane elements.” A plurality of membrane elements is apparent from the figures and the use of the term “membrane elements” throughout the specification.

The description of the mask body was amended to include the feature “comprising an interior surface and an exterior surface.” The phrases “mask interior” and “interior of the mask” can be found in the specification at page 3, line 24 and at page 2, line 12, respectively, as well as in the description of Figures 1-4. An interior surface and an exterior surface of a mask body, wherein the interior is clearly defined, are inherent features of the mask body.

The membrane elements were further defined “as partially overlapping lamellas” as supported in the specification at page 3 line 20. Moreover, the lamellas are disposed on the “exterior surface of the mask body” as illustrated in Figure 1.

Additionally, the feature “an inhalation opening” was included in claim 1. Inhalation openings are apparent in figures 1 and 4 and the term is supported in the specification at page 5, line 14, where it defines part 5 of the figures 1 and 4.

Claim 12 was amended to clearly illustrate the features of the claim as a method of using the respiratory mask defined in claim 1. The amended language is a restatement of original claim 12 and, additionally, finds support in the specification at page 4, lines 1-6.

Claim 13 further defines the inhalation opening feature of amended claim 1. The feature of an adaptation to be connected to a compressed gas source can be found in the specification at page 1, lines 16-21; page 2, lines 1-18; and page 3, lines 4-10. The requirement that the mask be adaptable for Continuous Positive Airway Pressure use necessitates connection to a compressed gas source.

Applicants submit that no new matter has been added.

### **Reply to Examiner's Statements**

Claims 1 and 6-12 were rejected as indefinite under 35 USC § 112, second paragraph. The Examiner specifically pointed to the use of the phrase "a large number" as a relative term. This term was replaced with the term "a plurality," a well recognized and often used claim term. This amendment traverses the Examiner's rejection of claims 1 and 6-11. Claim 12 was amended to clearly illustrate the features of the method of use of the device and it is submitted that claim 12, as amended, is not indefinite.

Claims 1 and 8 were rejected under 35 USC § 102(b) as being anticipated by Liang GB 2,264,060 ('060). Liang specifically teaches a respiratory mask comprised of a exhalation pipe 2 containing capillary tubes or pieces of film within the exhalation pipe. As amended, claim 1 clearly recites that the plurality of lamella membrane elements are disposed on the exterior surface of the mask. Liang teaches interior membrane elements that are capable of blocking a single air passage 18 and each of the amended claims recite a plurality of exterior membrane elements disposed on the exterior surface of the mask body as partially overlapping lamellas through which expired air can flow. It is submitted, therefore, that the rejections of claim 1 and 8 under 35 USC § 102 should be withdrawn.

Claims 6 and 7 stand rejected under 35 USC § 103(a) as being unpatentable over Liang '060 in view of Hans 5,320,096 ('096). Liang '060 neither discloses nor suggests a plurality of overlapping lamellas through which expired air can flow. Liang '060 teaches a single exhaust passage 18 at a distal end of exhaust pipe 2 that is blocked by interior capillary tubes or films. Further, it would not have been obvious to one skilled in the art, based on the limited description and drawings of the Liang '060 exhaust pipe 2, to provide the plurality of overlapping lamellas, disposed on the exterior of the mask body, through which expired air can flow, as now claimed.

Hans '096 is directed to a device for connection to a tracheal tube (col. 2, lines 52-57) that is useful for patients receiving respirator care for filtration of bacteria, virus, etc. from air to and from the patient.

It is asserted in the rejection of claims 6 and 7 that one of ordinary skill would use the strip material 36 (Fig. 6) of Hans '096 together with the exhalation system of Liang '060 for

the advantage of filtration of exhaled gas. Such a combination presumes connection of tube 13 of Hans '096 at air passage 18 of the Liang '060 exhaust pipe 2, in order to retain the Liang '060 blocked air passage (on inhaling) while adding the Hans '096 feature of filtered exhaled gas.

Presumably one skilled in the art could connect the Hans '096 device at the air passage 18 of the Liang '060 mask. However, Applicants' claims now require that the bendable membrane elements are disposed as partially overlapping lamellas and each of the strip materials 36 of Hans '096 are required to be separated from each other by air previous sheet materials 35 (36 inserted into the pleats of sheet material 35 – col. 4, lines 45-49). Thus, regardless of how cumbersome this combination would be, making it difficult on a mask, the combination does not meet the features of claims 6 and 7, or any remaining claims. Further, any attempt to alter the positioning of strip materials 36 would destroy the teachings of the Hans '096 device.

It is submitted, therefore, that the rejection of claims 6 and 7, based on Liang '060 in view of Hans '096, should be withdrawn.

Claims 9-12 stand rejected under 35 USC § 103(a) as being unpatentable over Liang '060 in view of Blake-Coleman 5,160,616 ('616). Blake-Coleman '616 does not disclose the deficiencies of the Liang '060 or Hans '096 prior art, as detailed above. Further, the teachings of Blake-Coleman are directed toward "industrial and laboratory separation processes" as part of the analytical and/or purification processes in the "biotechnological and pharmaceutical industries." Column 1, lines 6-8. It is submitted further, therefore, that it would not have been obvious to use the material of Blake-Coleman '616 in Applicants' claimed respiratory mask. Moreover, while Blake-Coleman '606 teaches a piezoelectric material, it does not teach the control of spring rigidity in a mask having overlapping lamellas on an exterior of the device. Specifically, Blake-Coleman '616 teaches a two piece filtration device wherein the holes through which a filtrate could pass are potentially occluded by the application of a current to a piezoelectric material. Column 2, lines 1-24. One of ordinary skill would recognize that a piezoelectric material changes the length of the material on, typically, one crystallographic axis. Therein, Blake-Coleman '606 teaches a sliding

occlusion device, not the control of the spring rigidity operational as shown in Applicants' Fig. 6, and as set forth in Applicants' claims.

It is submitted, therefore, that the rejection of claims 9-12, based on Liang '060 in view of Blake-Coleman '616, should be withdrawn. Early and favorable consideration is respectfully requested.

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